



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUN 2 2004

Michael K. Smith
Secretary of Administration
State of Vermont
Pavilion Office Building
109 State Street
Montpelier, VT 05609-0201

Re: Docket No. 2003P-0479/CP2

Dear Mr. Smith:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in the citizen petition you submitted to the Agency on behalf of the State of Vermont on December 12, 2003. The petition asks FDA to, among other things, issue regulations or otherwise commit to exercise its enforcement discretion to allow the Vermont State Employee Medical Benefit Plan to establish a program for the individual importation of prescription drugs from Canada.

FDA has been unable to reach a decision on the petition because it raises significant issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to the petition as soon as we have reached a decision on the petition's requests.

Sincerely,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

2003P-0479

LET 2